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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,597	08/20/2001	Iran Basil Shine	768-010453-	5844

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PERMAN & GREEN
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FAIRFIELD, CT 06824

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,597	SHINE ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/18/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to detect agglutination of a sample of cells by comparing the number of cells prior to and after the step of inducing a change in the shape of the cells so as to separate any agglutinated cells, does not reasonably provide enablement for a method of detecting agglutinated cells by inducing a change and detecting the resultant alteration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification, page 4, lines 3-15, states that:

By placing a whole blood sample into a typically 1:10,000 suspension, and causing cells which are approximately bi-concave discs to sphere, the effective surface area available for bonding diminishes. Sphering a cell increases the pace between antigen binding sites and increases the mean distance across which bonding occurs. The surface area available for bonding between cells decreases as cells sphere hence they lose bonding strength and separate. By recording the inducing pressure and the

number of cells (or quantities related to it) as they change with respect to the inducing pressure, agglutination can be detected, quantified and monitored. Cells which have agglutinated, when tested by this method, separate and thereby increase the cell count in a characteristic fashion. In a further step the sample is subject to mechanical agitation which tends to promote agglutination in normally shaped cells capable of agglutination but promotes separation of spherically shaped cells.

Nowehere in the specification is there a teaching of the method of claim 1. Specifically, the specification requires that a recording of the inducing pressure and the number of cells (or quantities related to it) *as they change* with respect to the inducing pressure, agglutination can be detected, quantified and monitored. The specification does not teach detecting only the end result (i.e., detecting the resultant alteration in the cell population.)

Alternatively the specification teaches measuring agglutination using a process which is also capable of testing how tightly agglutinated cells are bonded by measuring how much force is required to separate them. According to the specification at page 3, line 20 through page 4, line 3, this property depends upon antibodies interacting with the complement system. Agglutination of red blood cells is a function of the type and number of antigen combining sites on the surface of the cells, which bind with complementary IgG antibody molecules. The strength of agglutination is a function of the proximity of the binding sites on the cell surface.

Again, nowhere in the specification is there a teaching of the method of claim 1.

Also, the specification does not reasonably provide enablement for the step in claim 2. The specification on page 3, line 21 through page 4, line 15, describes that strength of agglutination is function of the proximity of the binding sites on the cell surface (page 4, lines 2-3) and that sphering a cell increases the space between antigen binding sites and increases the mean distance across which bonding occurs (page 4, lines 6-7) and that by recording the inducing pressure and the number of cells as they change with respect to the inducing pressure, agglutination can be detected, quantified and monitored (page 4, lines 9-11). However, the specification does not teach how the force required to separate agglutinated cells is measured.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chryssanthou, 4,130,395.

Chryssanthou discloses a method of detecting agglutination in a sample of cells (column 1, lines 44-47, column 4, lines 41-54), comprising the steps of inducing a change of the shape of the cells so as to separate agglutinated cells (column 4, lines 41-43 and lines 63-66; i.e., the agglutinated red blood cells will separate during the osmotic influx of water into the red blood cells which will cause them to swell and

eventually lyse) and detecting the resultant alteration in the cell population (column 2, line 28, and column 7, lines 57-58; i.e., the detection of the degree of osmotic lysis is the detection of the resultant alteration in cell population).

As to claim 2, the method comprises the step of measuring the force required to separate agglutinated cells (column 8, lines 24-29; i.e., measuring the hypotonic solutions, producing the osmotic pressure and hemolysis is the step of measuring the force required to separate agglutinated cells.)

As to claim 4, the cell sample is subject to an alteration to cause the cells to sphere (column 4, lines 63-66; the cells will sphere before they lyse).

As to claim 5, the alteration is a change in osmolality of a liquid medium in which the cells are suspended (column 4, lines42-45, an d lines 63-66; and column 8, lines 23-29).

As to claim 8, the method includes pretreating the sample of cells to induce agglutination (column 5, lines 12-13and lines 15-16)

As to claim 9, the cell sample is obtained from a source of whole blood (column 2, lines 3-11).

As to claim 10, the sample of cells are treated with antibodies from a different source (column 13, lines 63-64, and column 14, lines 55-57).

As to claims 11 and 12, the cells are treated in order to determine the blood type (column 1, lines 62-64; column 4, line 38).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chryssanthou, 4,130,395.

Chryssanthou discloses the invention substantially as claimed (see above), except for the specific temperature exposure of the sample.

Chryssanthou however discloses that the room temperature has been found to be suitable for carrying out the various steps of the method (column 2, lines 30-33). Thus, it would have been obvious that the temperature of the reagents can be warmed to room temperature (if the reagents that have been refrigerated for example, see column 13, lines 67-68), or cooled to room temperature if the reagents are warmer than room temperature.

Also, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chryssanthou, 4,130,395, in view of Lowke et al., 3,993,517.

Chryssanthou discloses the invention substantially as claimed (see above), except for the step wherein the antibodies from the different source are manufactured, or come from whole blood, plasma or serum.

Lowke, like Chryssanthou, also discloses a diagnostic assay using antibodies. Lokwe further discloses that specific antibodies can be prepared from animals immunized with a particular antigen, and that the antibodies can be obtained from mammals or avian sources (column 1, lines 43-45 and lines 62-67.) Thus, Lowke teaches that antibodies can be obtained from a different source and are manufactured or come from whole blood, plasma or serum. It would have been obvious that the antibodies used in the Chryssanthou assays can be obtained from the method taught by Lowke as a known means for producing antibodies for diagnostic assays.

Response to Arguments

Examiner acknowledges that the above claims were indicated in the previous Office action as having allowable subject matter. However, upon further consideration, Examiner believes the above rejections are proper.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brunhouse et al., 5,348,859, discloses a method for identifying and counting cells. Lancaster 4,185,964, discloses lysing reagents in the analysis of blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L

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3/07/04